Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Vitravene™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Vitravene™ is 1,738 days. Of this time, 1,598 days occurred during the testing phase of the regulatory review period, while 140 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* November 24, 1993. The applicant claims October 25, 1993, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 24, 1993, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* April 9, 1998. The applicant claims April 6, 1998, as the date the new drug application (NDA) for Vitravene™ (NDA 30–961) was initially submitted. However, FDA records indicate that NDA 30–961 was submitted on April 9, 1998.

3. *The date the application was approved:* August 26, 1998. FDA has verified the applicant's claim that NDA 30–961 was approved on August 26, 1998.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 954 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 27, 2000, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before July 25, 2000, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 23, 1999.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 00–1874 Filed 1–26–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0837]

Determination of Regulatory Review Period for Purposes of Patent Extension; Azopt™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Azopt™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Regulatory Policy Staff (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Azopt™ (brinzolamide). Azopt™ is indicated for the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Azopt™ (U.S. Patent No. 5,378,703) from Alcon Laboratories, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 11, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Azopt™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Azopt™ is 2,049 days. Of this time, 1,620 days occurred during the testing phase of the regulatory review period, while 429 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* August 23, 1992. The applicant claims July 24, 1992, as the date the investigational new drug

application (IND) became effective. However, FDA records indicate that the IND effective date was August 23, 1992, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* January 28, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for Azopt™ (NDA 20–816) was initially submitted on January 28, 1997.

3. *The date the application was approved:* April 1, 1998. FDA has verified the applicant's claim that NDA 20–816 was approved on April 1, 1998.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 579 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 27, 2000, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before July 25, 2000, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 23, 1999.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 00–1875 Filed 1–26–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Quality of Life Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Quality of Life Subcommittee of the Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 10, 2000, 8 a.m. to 4 p.m.

Location: Ramada Inn, Embassy Ballroom, 8400 Wisconsin Ave., Bethesda, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: The Quality of Life Subcommittee of the Oncologic Drugs Advisory Committee will discuss issues related to the study of quality of life for patients enrolled in cancer trials. Specific potential areas for discussion include definition of patient centered outcomes, clinical significance and interpretation of study results, and approaches to the statistical analysis of data.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 3, 2000. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:45 a.m., and between approximately 12:45 p.m. and 1:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 3, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation. After the scientific presentations, a 30-minute open public session may be conducted for interested persons who have submitted their request to speak by February 3, 2000, to address issues specific to the topic before the committee.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 18, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–1866 Filed 1–26–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–5333]

Plans to Develop Guidance on Submitting an Archival Copy of an ANDA in Electronic Format; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Office of Generic Drugs (OGD), within its Center for Drug Evaluation and Research, is announcing plans to develop guidance on submitting an archival copy of a complete abbreviated new drug application (ANDA) in electronic format. OGD has encouraged the electronic submission of some types of data on a voluntary basis since 1997. However, these submissions are not archivable and are made in addition to a complete paper submission. OGD plans to expand its electronic data submission program to include all parts of the ANDA, so that the archivable electronic submission can replace the paper submission as the ANDA of record. OGD is soliciting comments from the public on its current program so it can consider these comments as it develops guidance for industry on the submission of complete, archivable ANDA's in electronic format. A draft guidance will be developed and made available for public comment. The ANDA electronic submission guidance will be one in a series of guidances the agency is developing to enable sponsors to submit archivable regulatory submissions in electronic format.